

Remarks

Claims 56-110 are pending in the subject application. Claims 56-58 and 61-92 read on the species election required by the Office Action (and claims 56-58 and 61-85 read on species elected for Group I). Accordingly, claims 56-110 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants respectfully traverse the Restriction Requirement set forth in the previous Office Action. As the Examiner is aware, this application is a national stage application and is subject to the unity of invention rules for restriction. The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Additionally, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression “special technical features” is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The Restriction Requirement argues that the teachings of Cosenza *et al.* (*Protein Sciences*, 2000, Vol. 9, pp. 916-926) anticipates the claimed subject-matter and that, accordingly, the claimed invention does not define a contribution over the prior art. Applicants respectfully traverse.

As the Patent Office is aware, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound, particularly if the claimed compound is produced by a process developed later in time. *In re Hoeksema*, 399 F.2d 269, 158 U.S.P.Q. 596 (C.C.P.A. 1968). In this case, it is respectfully submitted that Cosenza *et al.* (2000) cannot anticipate the claimed invention as the teachings of the reference, while naming the claimed conformer, indicated that the actual IL-7 conformer produced and characterized in the reference contained three disulfide

bridges (Cys3-142, Cys35-130 and Cys48-93, the bond assignments being made by mass spectroscopy; see, for example, the end of the introduction and the end of the section entitled “Construction of an IL-7 structural hypothesis” at page 918). Thus, while Cosenza *et al.* mention this conformer in Figure 3B, it is only referred to as the 1996 Kroemer *et al.* hypothesis, a conformational hypothesis made via computational chemistry using IL-4 as a template. However Cosenza *et al.* does not teach the production of the claimed conformer, does not teach how one is to make the claimed conformer and clearly explains that he does not believe that this conformer exists in view of the mass spectrophotometric data, the analysis of mutated IL-7 variants described in both the 1997 and 2000 papers authored by Cosenza *et al.* and the results of bioassays conducted in the publications. Indeed, the conformation adopted by Cosenza *et al.* is that which is described in the *Protein Data Bank at Brookhaven National Laboratory*, with PDB identification code IL-7. However, the present inventors have shown that the claimed Cys3-93, Cys35-130 and Cys48-142 IL-7 conformer is the preferred conformer for therapeutic use and the major molecular species within the claimed IL-7 drug substance, thus providing a significant contribution over the prior art. Accordingly, reconsideration and withdrawal of the Restriction Requirement is respectfully requested as the reference cited to demonstrate that the claimed invention does not represent a contribution of the prior art (Cosenza *et al.*) fails to anticipate the claimed invention, does not meet the legal requirements for an anticipatory reference and, thus, cannot be used as evidence that the claimed invention does not represent a contribution over the prior art.

Applicants believe that the pending claims are in condition for allowance and such action is respectfully requested.

Applicants also invite the Examiner to call the undersigned if clarification is needed or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

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